US011213346B2

(12) **United States Patent**
Jimenez

(10) **Patent No.: US 11,213,346 B2**
(45) **Date of Patent: *Jan. 4, 2022**

(54) **SYSTEM AND METHOD FOR SELECTIVELY ENERGIZING CATHETER ELECTRODES**

(71) Applicant: **BIOSENSE WEBSTER, INC.**, Irvine, CA (US)

(72) Inventor: **Eduardo Jimenez**, Paramount, CA (US)

(73) Assignee: **BIOSENSE WEBSTER, INC.**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 183 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **16/357,230**

(22) Filed: **Mar. 18, 2019**

(65) **Prior Publication Data**

US 2019/0209238 A1 Jul. 11, 2019

Related U.S. Application Data

(63) Continuation of application No. 15/811,496, filed on Nov. 13, 2017, now Pat. No. 10,231,780, which is a (Continued)

(51) **Int. Cl.**
A61B 18/12 (2006.01)
A61B 18/14 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 18/1492*** (2013.01); ***A61B 18/1206*** (2013.01); ***A61B 18/1233*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 18/1206; A61B 18/1233; A61B 18/1492; A61B 2018/00029;
(Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,365,639 A 12/1982 Goldreyer
4,532,924 A 8/1985 Auth et al.
(Continued)

FOREIGN PATENT DOCUMENTS

CA 2 285 342 10/1998
EP 0 974 936 1/2000
(Continued)

OTHER PUBLICATIONS

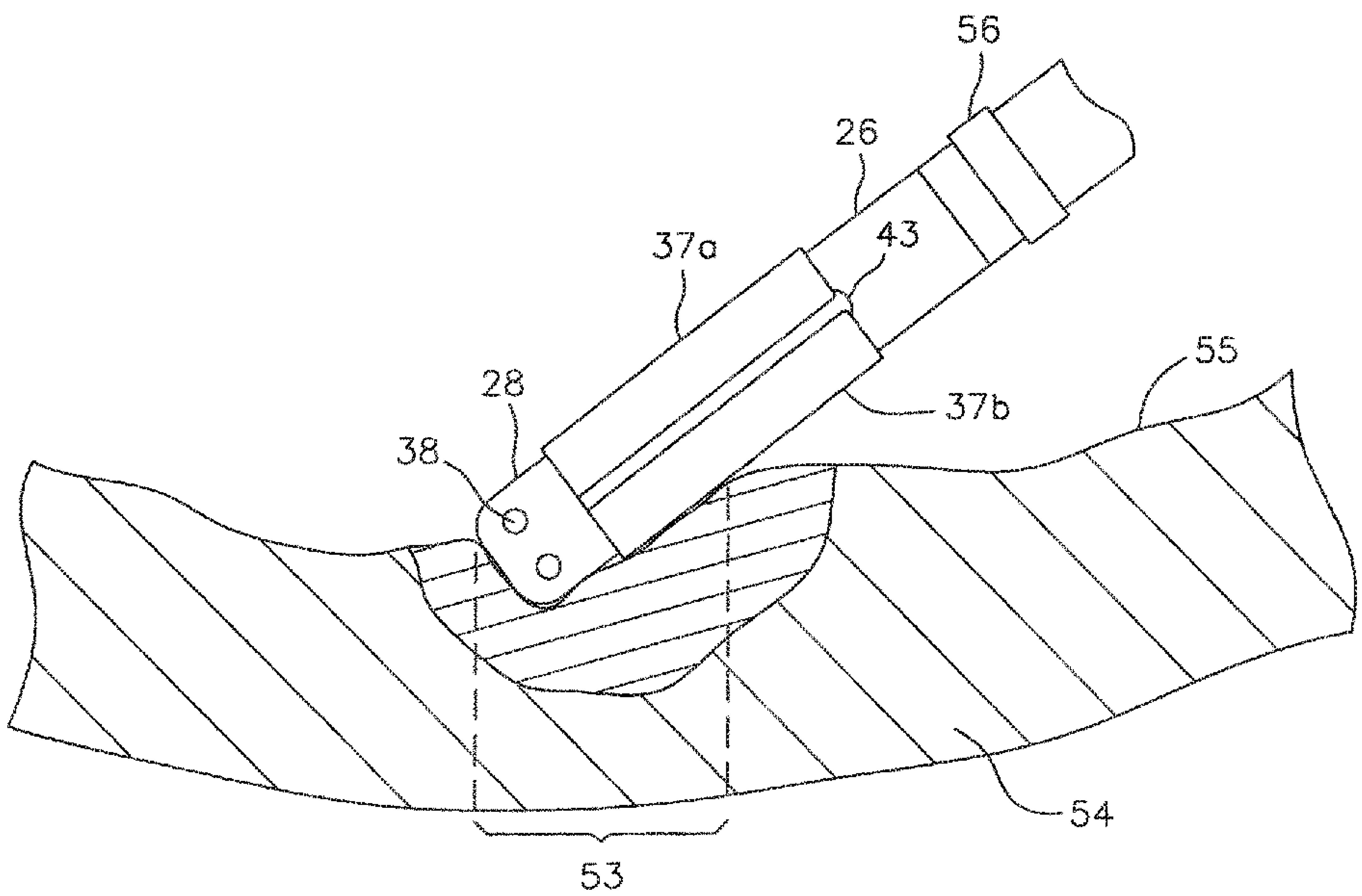
EP Communication dated Apr. 2, 2007 for EP Application No. 06256634.4 enclosing Partial European Search Report completed Mar. 19, 2007, 8 pages.

Primary Examiner — Daniel W Fowler
(74) *Attorney, Agent, or Firm* — Lewis Roca Rothgerber Christie LLP

(57) **ABSTRACT**

The present invention is directed to a system, a method and a catheter that provide improved ablation capabilities and improved energy efficiency by selectively energizing catheter electrodes on the basis of impedance measurements. In particular, the invention is directed to the selective energization of catheter radial electrodes that together with a tip electrode form a generally continuous tissue contact surface, wherein the selection is made on the basis of impedance measurement as an indication of the amount of tissue contact of each radial electrode.

20 Claims, 12 Drawing Sheets



Related U.S. Application Data

continuation of application No. 15/369,781, filed on Dec. 5, 2016, now Pat. No. 9,814,524, which is a continuation of application No. 14/985,239, filed on Dec. 30, 2015, now Pat. No. 9,510,893, which is a continuation of application No. 14/081,957, filed on Nov. 15, 2013, now Pat. No. 9,226,793, which is a continuation of application No. 12/985,254, filed on Jan. 5, 2011, now Pat. No. 8,603,085, which is a continuation of application No. 11/322,591, filed on Dec. 30, 2005, now Pat. No. 7,879,029.

(51) **Int. Cl.**

A61B 34/20	(2016.01)
A61M 25/00	(2006.01)
A61M 25/01	(2006.01)
A61B 17/00	(2006.01)
A61B 18/00	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 34/20*** (2016.02); ***A61M 25/005*** (2013.01); ***A61M 25/0147*** (2013.01); *A61B 2017/00026* (2013.01); *A61B 2018/00029* (2013.01); *A61B 2018/00351* (2013.01); *A61B 2018/00577* (2013.01); *A61B 2018/00642* (2013.01); *A61B 2018/00702* (2013.01); *A61B 2018/00875* (2013.01); *A61B 2018/00904* (2013.01); *A61B 2018/00988* (2013.01); *A61B 2018/124* (2013.01); *A61B 2018/1467* (2013.01); *A61B 2034/2051* (2016.02)

(58) **Field of Classification Search**

CPC A61B 2018/00351; A61B 2018/00577; A61B 2018/00642; A61B 2018/00702; A61B 2018/00875; A61B 2018/00904; A61B 2018/00988; A61B 2018/124; A61B 2018/1467

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,630,611	A		12/1986	King	
4,660,571	A		4/1987	Hess et al.	
5,078,714	A		1/1992	Katims	
5,341,807	A		8/1994	Nardella	
5,391,199	A		2/1995	Ben-Haim	
5,398,683	A		3/1995	Edwards et al.	
5,423,808	A	*	6/1995	Edwards	A61B 18/12 606/34
5,443,489	A		8/1995	Ben-Haim	
5,447,529	A		9/1995	Marchlinski et al.	
5,462,521	A	*	10/1995	Brucker	A61M 25/0068 604/20
5,462,545	A	*	10/1995	Wang	A61B 18/1492 600/373
5,469,857	A		11/1995	Laurent et al.	
5,480,422	A		1/1996	Ben-Haim	
5,546,951	A		8/1996	Ben-Haim	
5,558,091	A		9/1996	Acker et al.	
5,568,809	A		10/1996	Ben-Haim	
5,662,108	A		9/1997	Budd et al.	
5,673,704	A		10/1997	Marchlinski et al.	
5,718,701	A		2/1998	Shai et al.	
5,735,847	A	*	4/1998	Gough	A61N 1/06 606/41
5,738,096	A		4/1998	Ben-Haim	
5,755,761	A		5/1998	Obino	
5,836,874	A		11/1998	Swanson et al.	
5,836,990	A		11/1998	Li	
5,891,095	A		4/1999	Eggers et al.	
5,935,079	A		8/1999	Swanson et al.	
5,964,757	A		10/1999	Ponzi	
6,210,406	B1		4/2001	Webster	
6,217,574	B1		4/2001	Webster	
6,226,542	B1		5/2001	Reisfeld	
6,241,742	B1		6/2001	Fleischman et al.	
6,301,496	B1		10/2001	Reisfeld	
6,546,270	B1		4/2003	Goldin et al.	
6,569,160	B1		5/2003	Goldin et al.	
6,592,580	B1		7/2003	Stocked	
6,602,242	B1		8/2003	Fung et al.	
6,690,963	B2		2/2004	Ben-Haim et al.	
6,799,064	B1		9/2004	Hassett	
7,879,029	B2		2/2011	Jimenez	
8,603,085	B2		12/2013	Jimenez	
9,226,793	B2		1/2016	Jimenez	
9,510,893	B2		12/2016	Jimenez	
2002/0077627	A1	*	6/2002	Johnson	A61B 18/1477 606/41
2002/0165530	A1	*	11/2002	Harano	A61B 18/1206 606/32
2004/0181139	A1	*	9/2004	Falwell	A61B 5/287 600/374
2006/0259027	A1	*	11/2006	Kwan	A61B 18/148 606/41

FOREIGN PATENT DOCUMENTS

EP	1 502 542 A1	2/2005
JP	2000-201949	7/2000
JP	2001-510354	7/2001
JP	2002-65626	3/2002
WO	WO 95/02995	2/1995
WO	WO 96/05768	2/1996
WO	WO 97/45157	12/1997

* cited by examiner

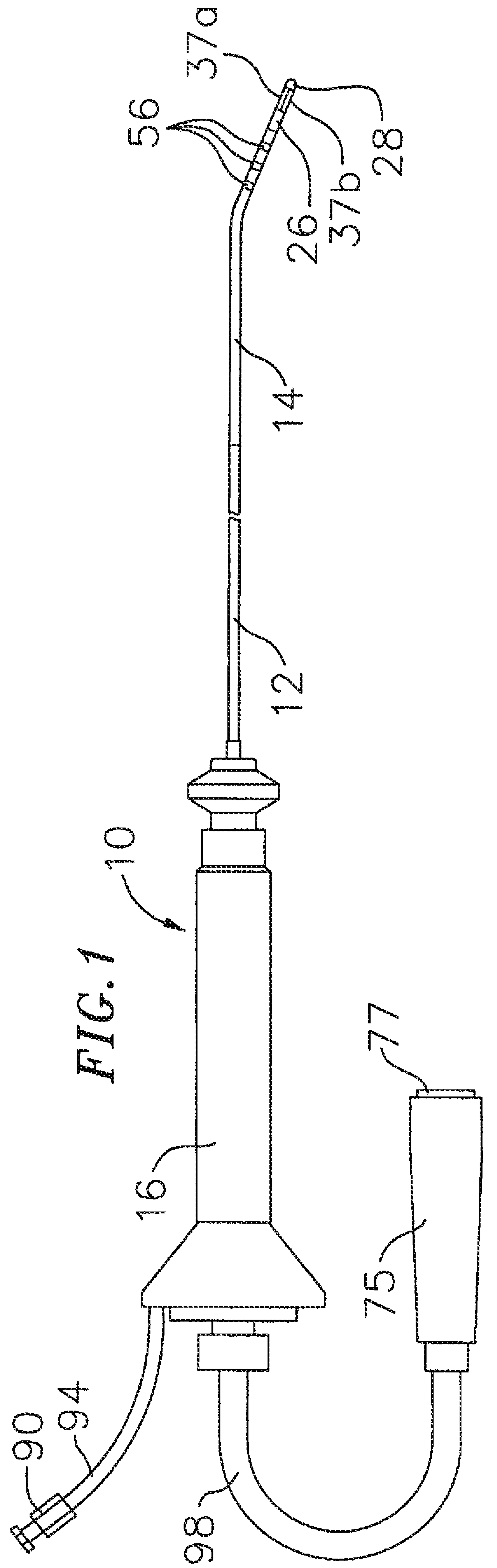
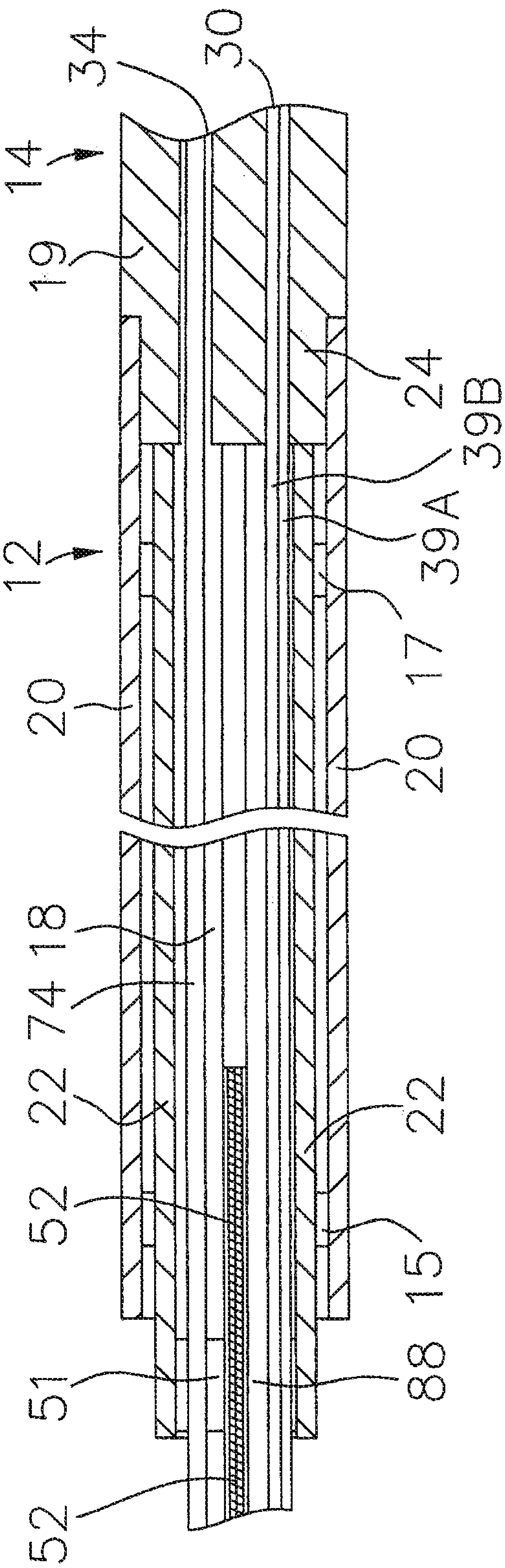


FIG. 1

FIG. 2



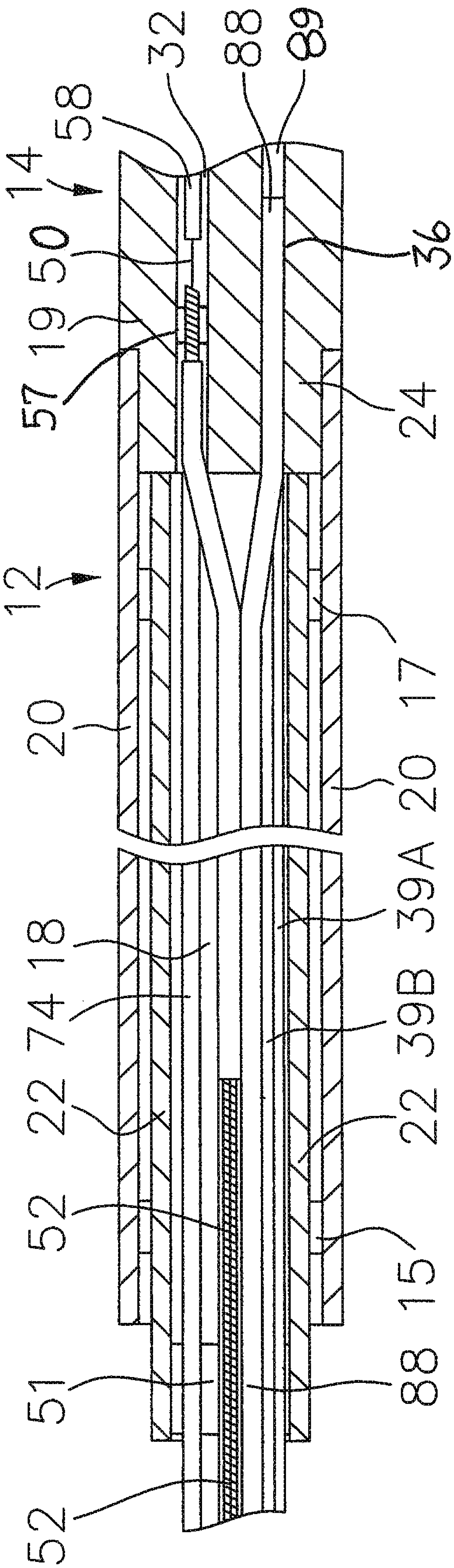
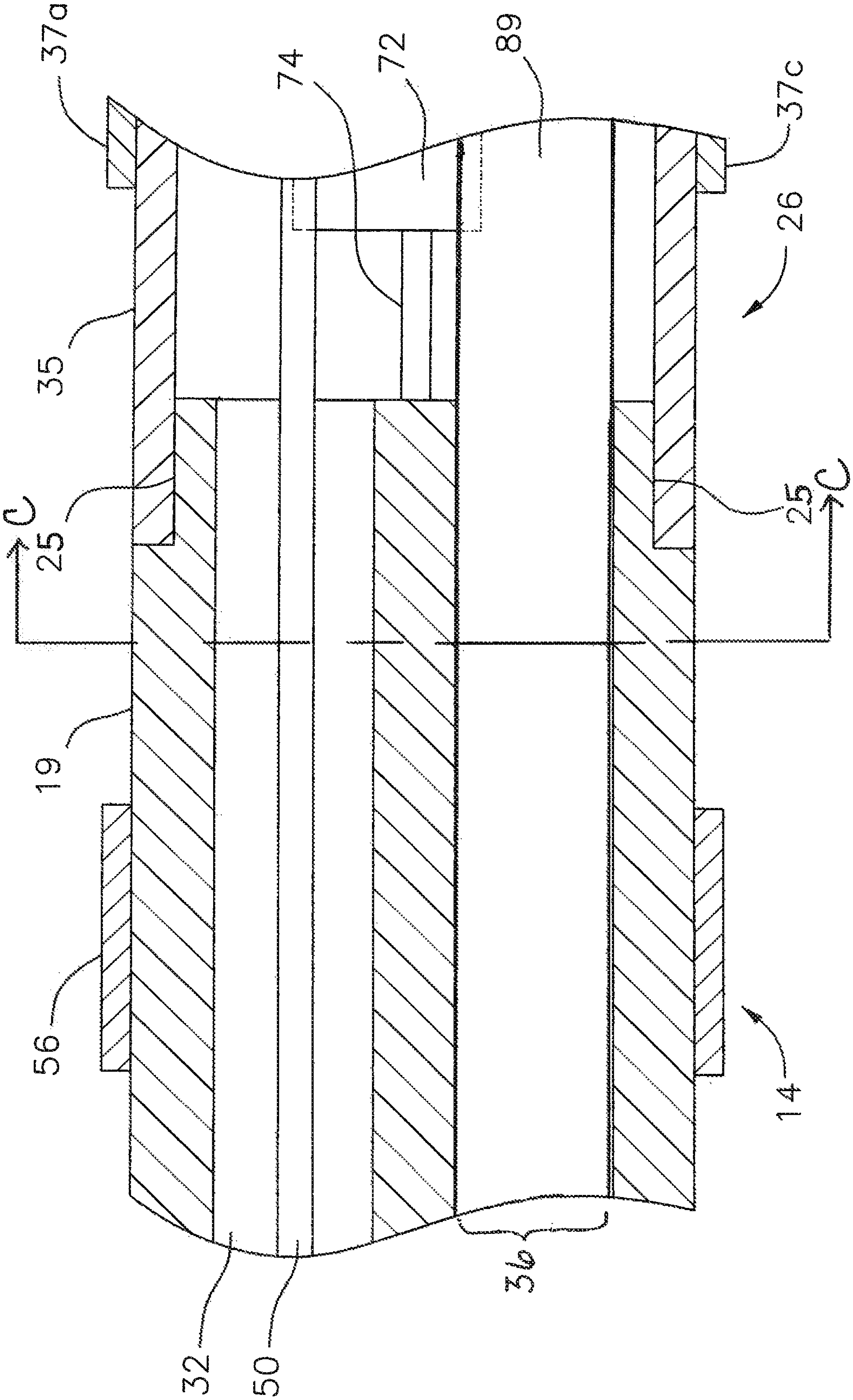

14
58
32
88
89
36
50
19
57
24
12
17
20
20
39A
18
74
39B
22
22
52
15
51
88
52

FIG. 2A

FIG. 3A



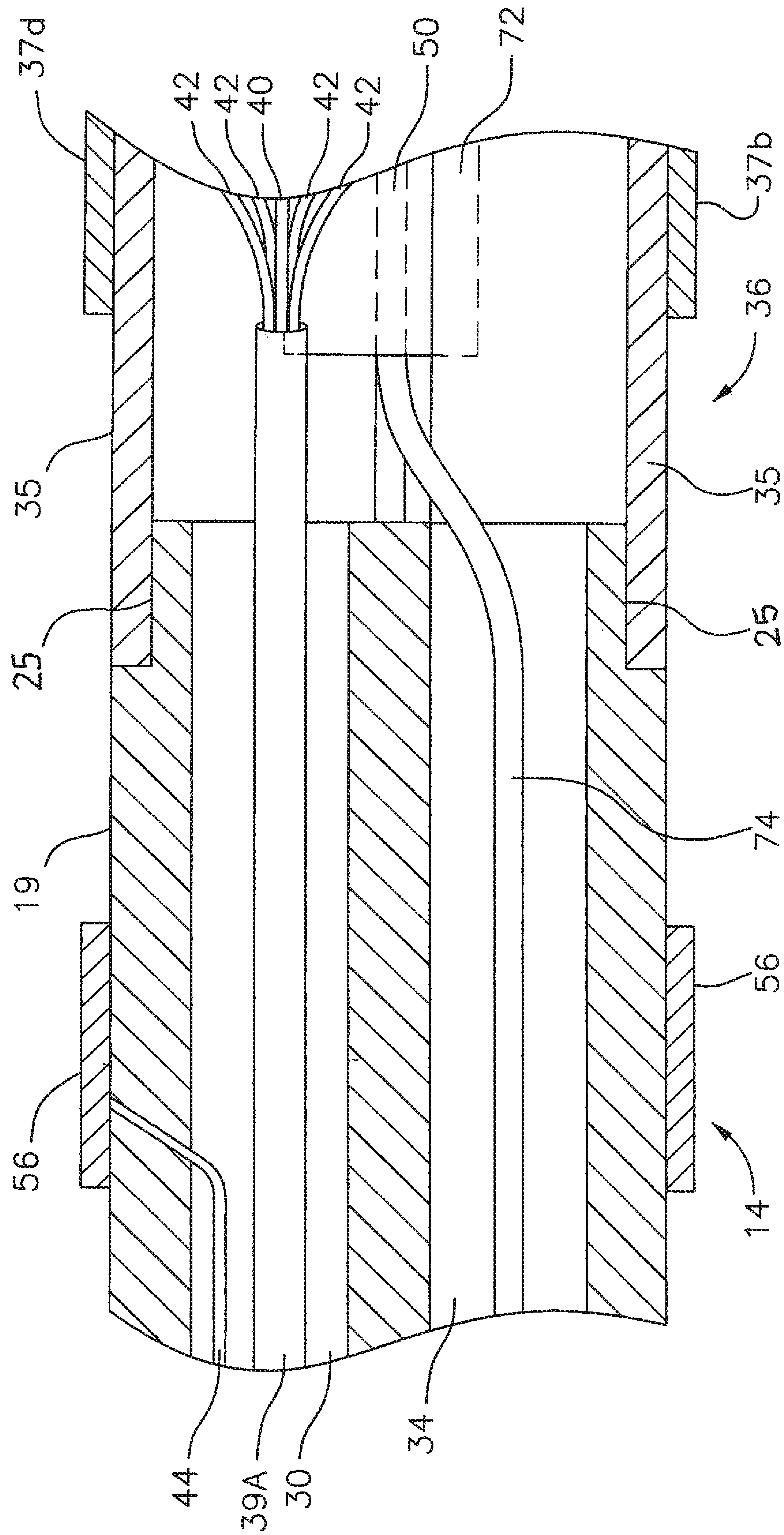


FIG. 3B

FIG. 3C

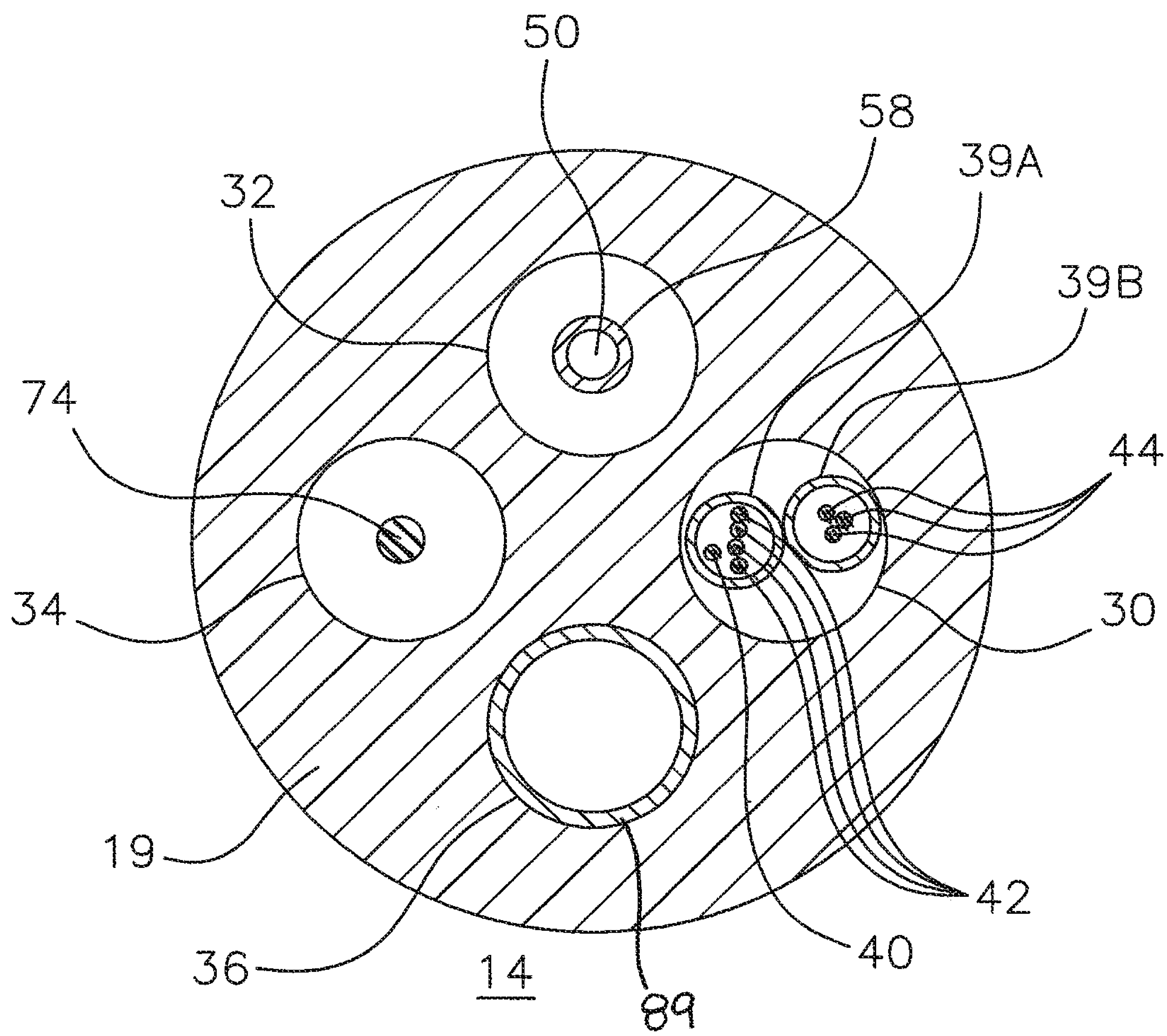


FIG. 4A

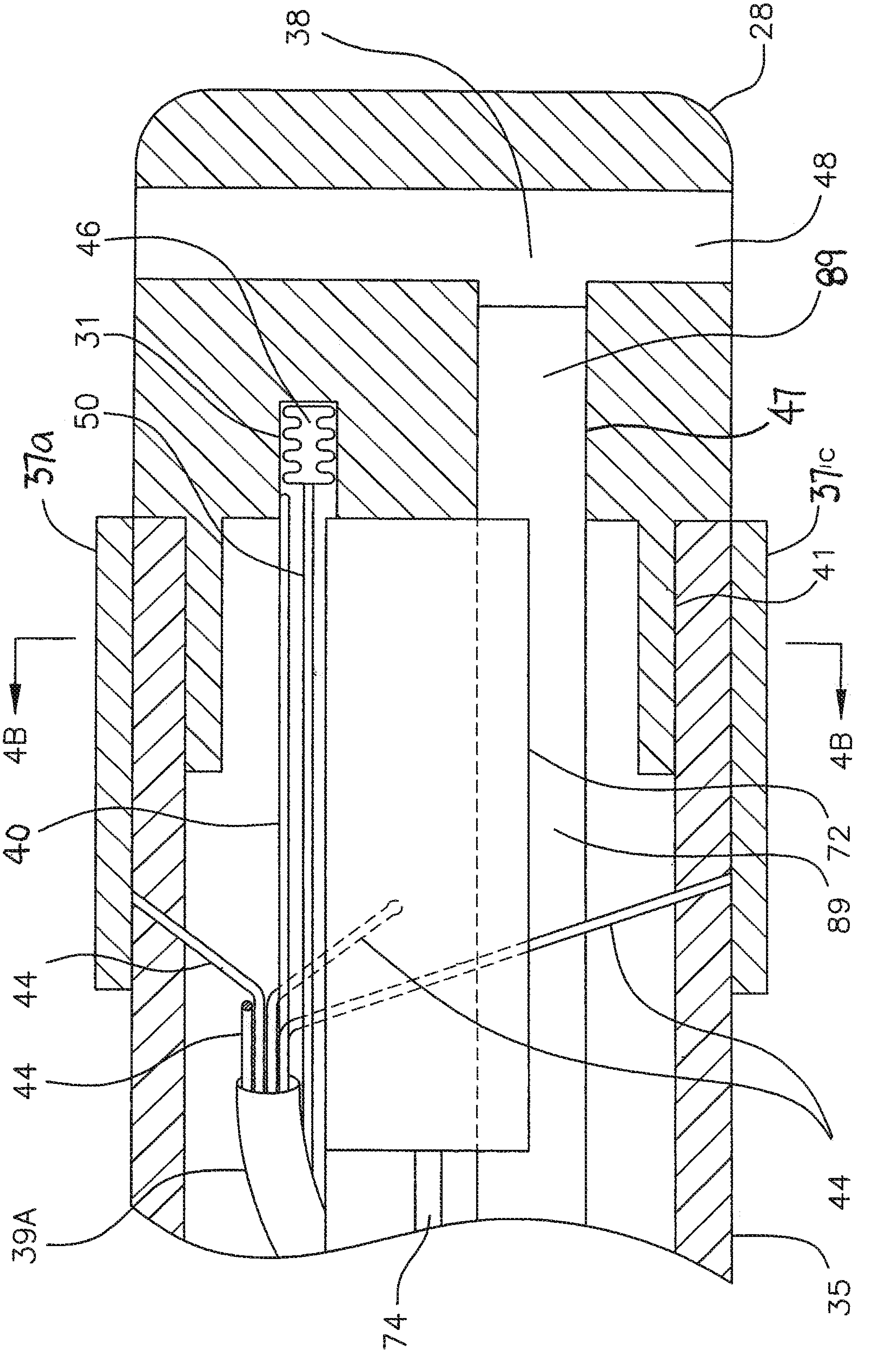
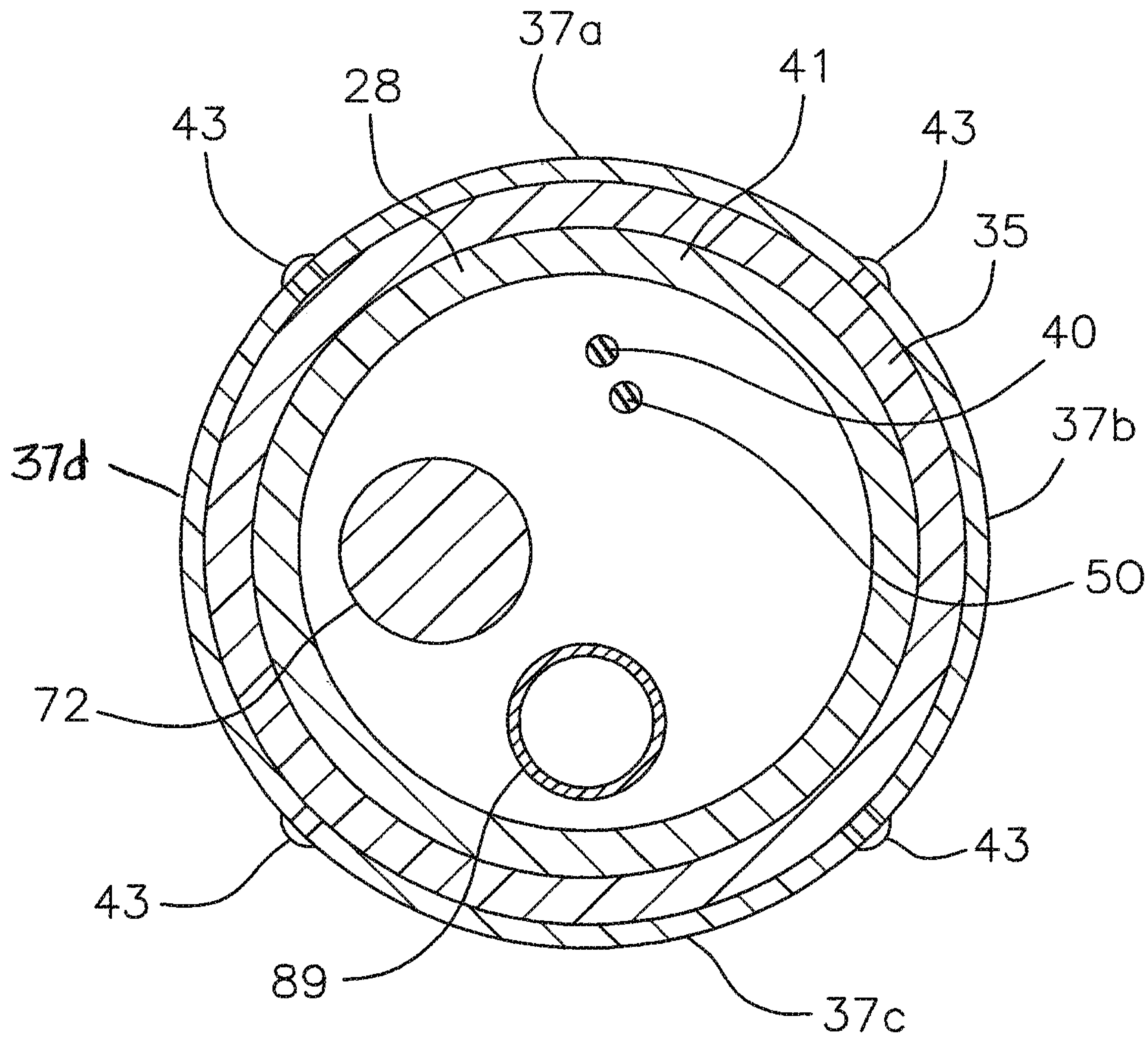


FIG. 4B



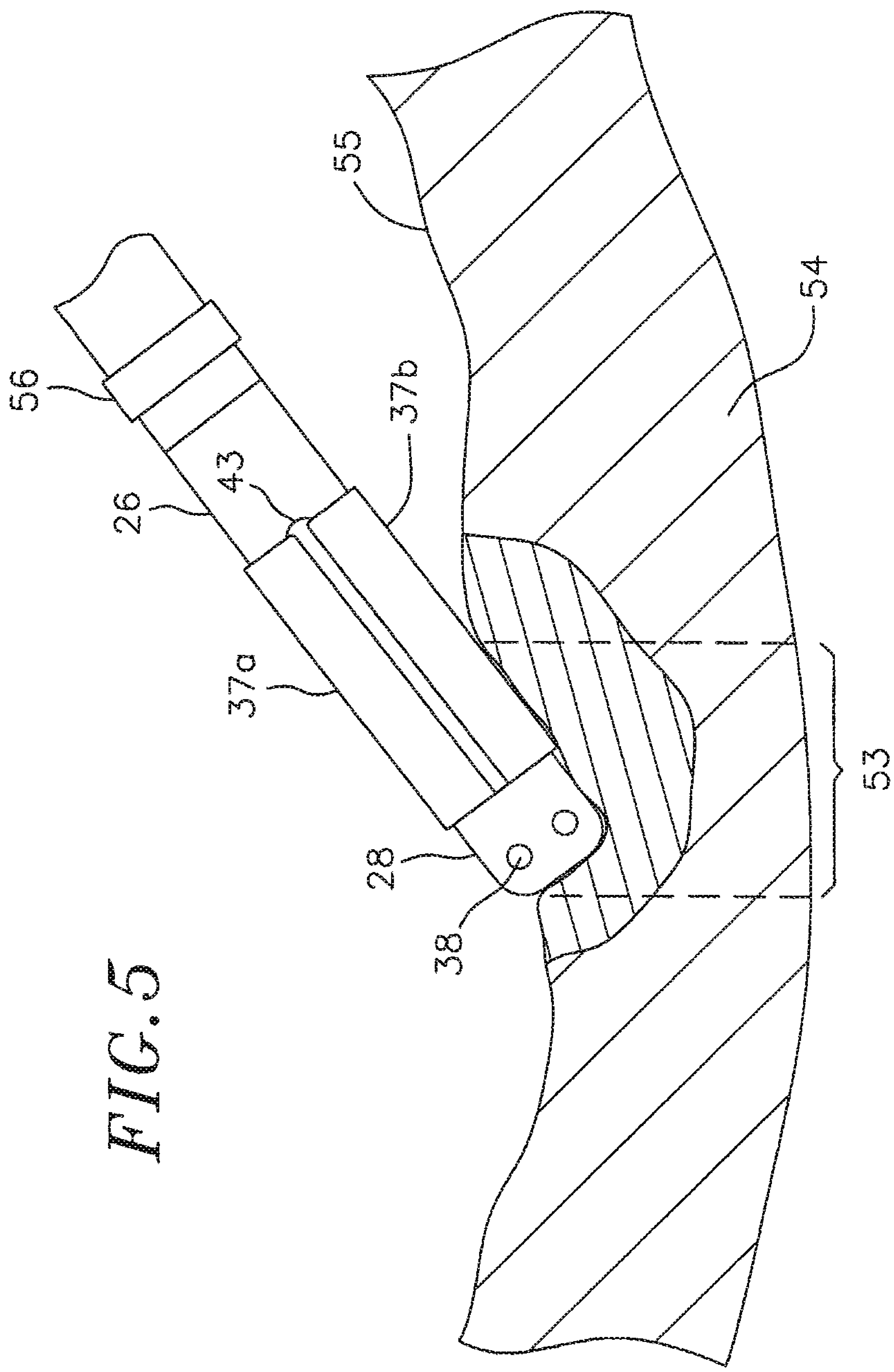


FIG. 5

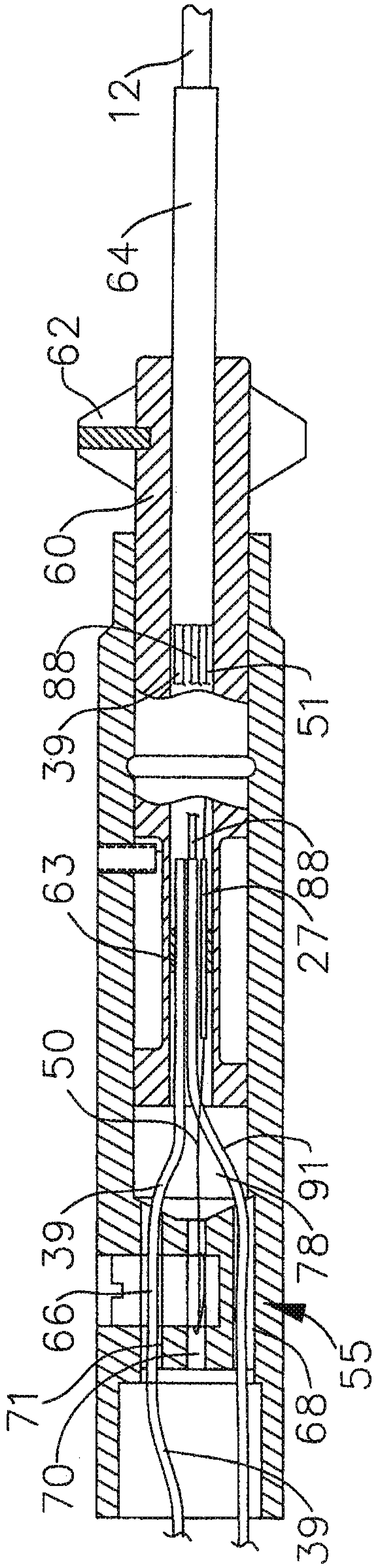


FIG. 6

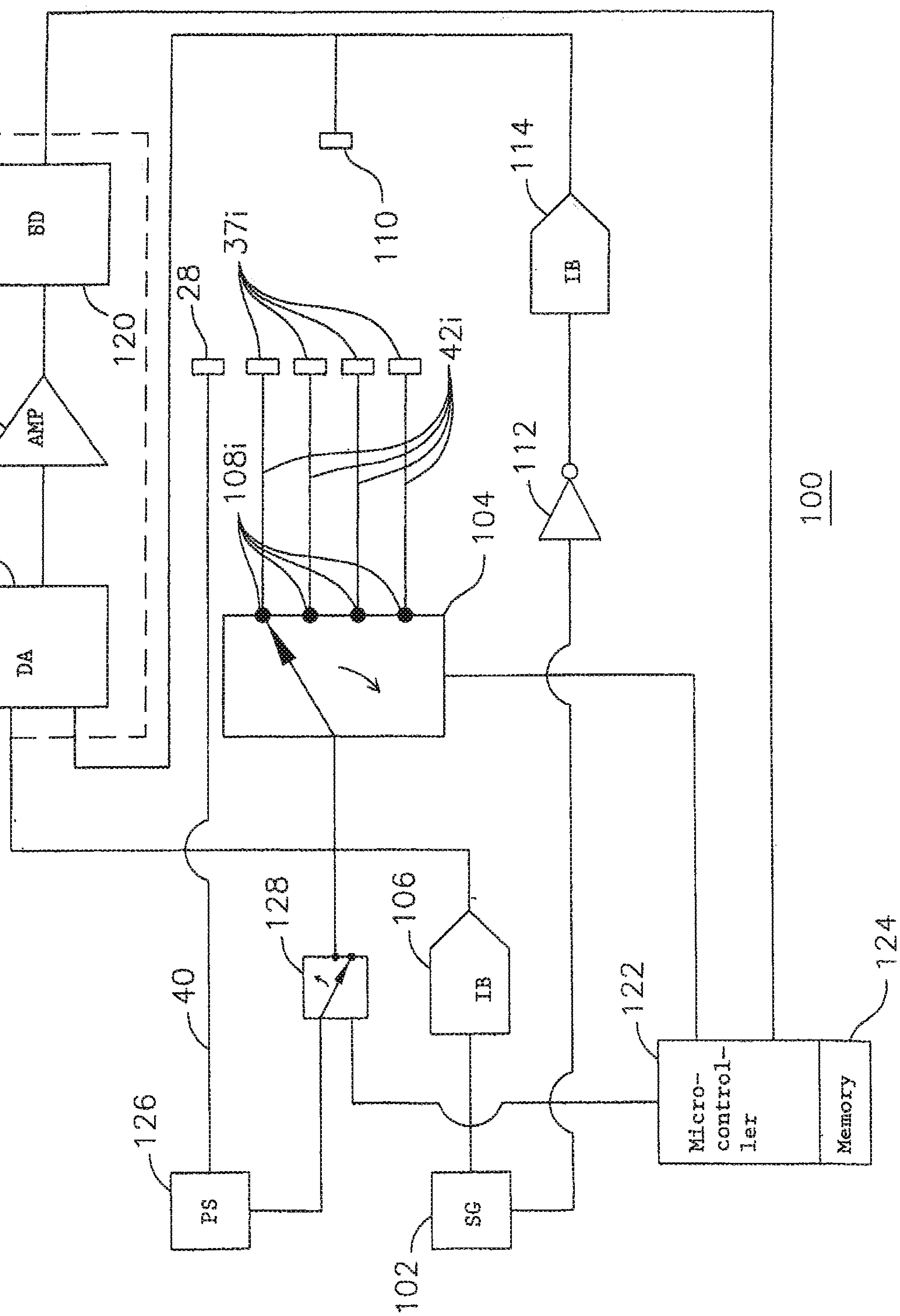
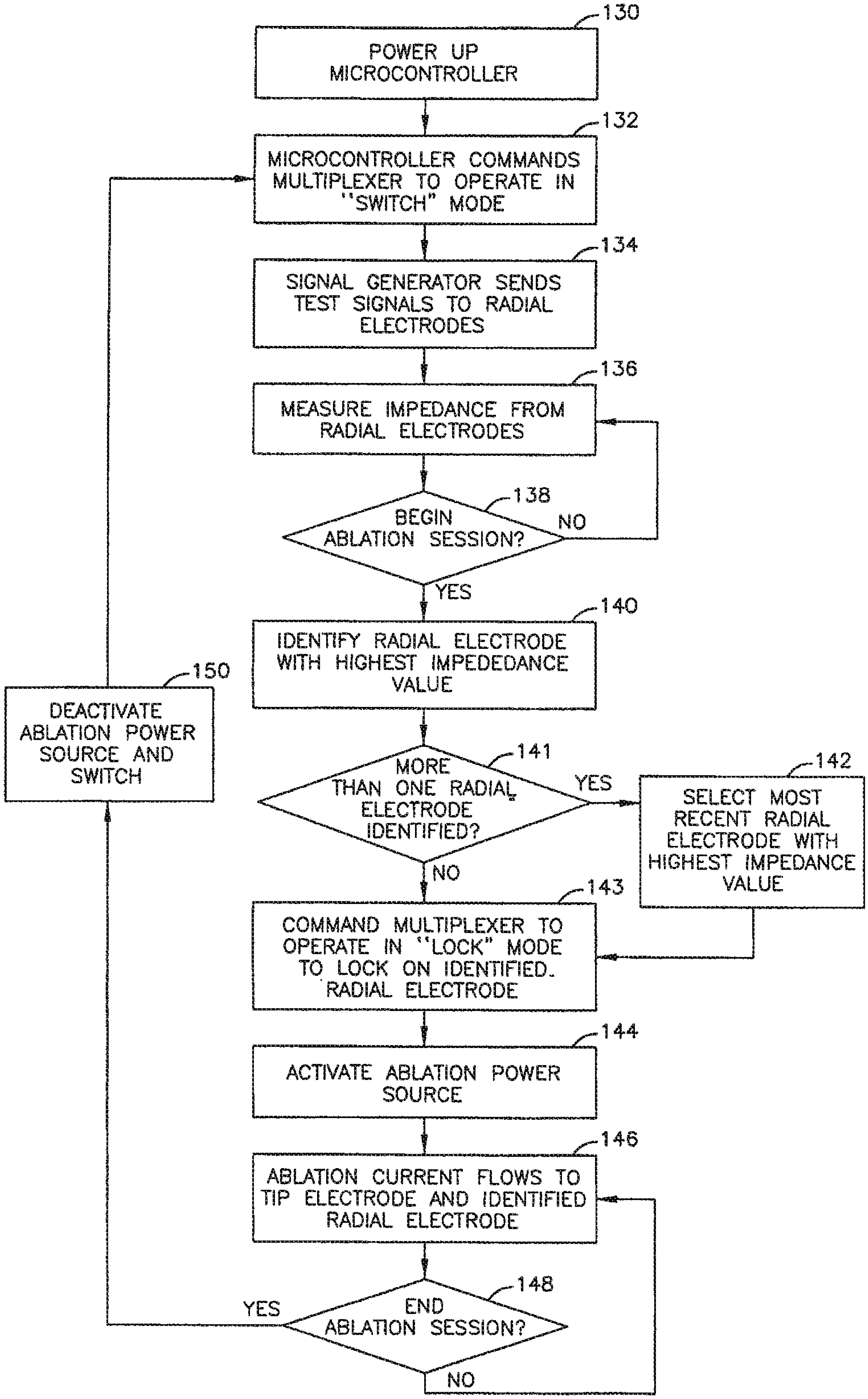

115 (TMC)
DA
116
AMP
118
BD
120
28
37i
110
114
IB
42i
108i
104
112
100
128
106
IB
40
126
PS
SG
102
122
Micro-
control-
ler
Memory
124

FIG. 7

FIG. 8


130
POWER UP MICROCONTROLLER
132
MICROCONTROLLER COMMANDS MULTIPLEXER TO OPERATE IN "SWITCH" MODE
134
SIGNAL GENERATOR SENDS TEST SIGNALS TO RADIAL ELECTRODES
136
MEASURE IMPEDANCE FROM RADIAL ELECTRODES
138
BEGIN ABLATION SESSION?
NO
YES
140
IDENTIFY RADIAL ELECTRODE WITH HIGHEST IMPEDEDANCE VALUE
141
MORE THAN ONE RADIAL ELECTRODE IDENTIFIED?
YES
142
SELECT MOST RECENT RADIAL ELECTRODE WITH HIGHEST IMPEDANCE VALUE
NO
143
COMMAND MULTIPLEXER TO OPERATE IN "LOCK" MODE TO LOCK ON IDENTIFIED RADIAL ELECTRODE
144
ACTIVATE ABLATION POWER SOURCE
146
ABLATION CURRENT FLOWS TO TIP ELECTRODE AND IDENTIFIED RADIAL ELECTRODE
148
END ABLATION SESSION?
YES
NO
150
DEACTIVATE ABLATION POWER SOURCE AND SWITCH

SYSTEM AND METHOD FOR SELECTIVELY ENERGIZING CATHETER ELECTRODES

CROSS-REFERENCE TO RELATED APPLICATION(S)

This application is a continuation of and claims priority to and the benefit of U.S. patent application Ser. No. 15/811,496 filed Nov. 13, 2017, issued as U.S. Pat. No. 10,231,780, which is a continuation of and claims priority to and the benefit of U.S. patent application Ser. No. 15/369,781 filed Dec. 5, 2016, issued as U.S. Pat. No. 9,814,524, which is a continuation of and claims priority to and the benefit of Ser. No. 14/985,239 filed Dec. 30, 2015, issued as U.S. Pat. No. 9,510,893, which is a continuation of and claims priority to and the benefit of U.S. patent application Ser. No. 14/081,957 filed Nov. 15, 2013, issued as U.S. Pat. No. 9,226,793, which is a continuation of and claims priority to and the benefit of U.S. patent application Ser. No. 12/985,254, filed Jan. 5, 2011, issued as U.S. Pat. No. 8,603,085, which is a continuation of and claims priority to and the benefit of U.S. patent application Ser. No. 11/322,591, filed Dec. 30, 2005, now U.S. Pat. No. 7,879,029, the entire contents of all of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention is directed to a catheter for electric diagnosis and treatment of the heart, and more particularly to a catheter for mapping and ablation.

BACKGROUND OF THE INVENTION

Cardiac arrhythmias, the most common of which is ventricular tachycardia (VT), are a leading cause of death. In a majority of patients, VT originates from a 1 mm to 2 mm lesion located close to the inner surface of the heart chamber. One of the treatments for VT comprises mapping the electrical pathways of the heart to locate the lesion followed by ablation of the active site.

U.S. Pat. No. 5,546,951; U.S. patent application Ser. No. 08/793,371; and PCT application WO 96/05768, which are incorporated herein in their entirety by reference, disclose methods for sensing an electrical property of heart tissue such as local activation time as a function of the precise location within the heart. The data are acquired by advancing into the heart one or more catheters that have electrical and location sensors in their distal tips. The precise three-dimensional location of the catheter tip is ascertained by the location sensor contained therein. The location sensor operates by generating signals that are responsive to its precise location within an externally generated non-ionizing field such as an electromagnetic field. Simultaneous with the acquisition of location information, electrical information is also acquired by at least one electrode contained at the catheter distal tip. Accurate sensing of location and electrical information by sensors contained in the catheter generally requires a high degree of confidence that a catheter electrode is in contact with the tissue.

Methods of creating a map of the electrical activity of the heart based on these data are disclosed in U.S. patent application Ser. Nos. 09/122,137 and 09/357,559 filed on Jul. 24, 1998 and Jul. 22, 1999, respectively, and in European Patent Application 974,936 which are also incorporated herein in their entirety by reference. In clinical settings, it is not uncommon to accumulate data at 100 or more sites within the heart to generate a detailed, comprehensive map of heart chamber electrical activity. The use of the location sensors as hereinabove described is highly useful in providing a detailed and accurate map of the heart chamber's activity.

Catheters containing position or location sensors may also be used to determine the trajectory of points on the cardiac surface. These trajectories may be used to infer mechanical motion characteristics such as the contractility of the tissue. As disclosed in U.S. Pat. No. 5,738,096 which is incorporated herein in its entirety by reference, maps depicting such motion characteristics, which may be superimposed with maps depicting local electrical information, may be constructed when the trajectory information is sampled at a sufficient number of points in the heart. Accurate maps of such motion characteristics again require confidence that the data are acquired when the catheter tip is in contact with the cardiac tissue.

The detailed maps generated as hereinabove described may serve as the basis for deciding on a therapeutic course of action, for example, tissue ablation, to alter the propagation of the heart's electrical activity and to restore normal heart rhythm. In cardiac ablation, energy, typically in the radiofrequency (RF) range, is supplied at selected points on the intracardiac surface by a catheter having an ablation electrode at its distal tip. Ablation is effected by bringing the distal tip electrode into contact with the locus of aberrant electrical activity and by initiating the delivery of RF energy through the distal tip electrode from an external RF generator in communication with the distal tip electrode. Ablation is most effectively performed when the distal tip electrode is in contact with the cardiac wall. Absence of contact or poor contact of the tip electrode with the heart wall leads to dissipation of the RF energy in the blood, as well as possible fouling of the tip electrode with the concomitant possibility of blood clot formation. Accordingly, it is important that both mapping and ablation be accompanied by methods and systems for detecting and ensuring electrode-tissue contact.

A number of references have reported methods to determine electrode-tissue contact, including U.S. Pat. Nos. 5,935,079; 5,891,095; 5,836,990; 5,836,874; 5,673,704; 5,662,108; 5,469,857; 5,447,529; 5,341,807; 5,078,714; and Canadian Patent Application 2,285,342. A number of these references, e.g., U.S. Pat. Nos. 5,935,079, 5,836,990, 5,447,529, and 6,569,160 determine electrode-tissue contact by measuring the impedance between the tip electrode and a return electrode. As disclosed in the '160 patent, the entire disclosure of which is hereby incorporated by reference, it is generally known that impedance through blood is generally lower that impedance through tissue. Accordingly, tissue contact has been detected by comparing the impedance values across a set of electrodes to pre-measured impedance values when an electrode is known to be in contact with tissue and when it is known to be in contact only with blood.

A disadvantage of typical ablation electrodes is that it is sometimes difficult to accurately predict lesion size because the lesion size can vary depending on the orientation of the ablation electrode. For example, typically a 7 French catheter (having an outer diameter of just over 2 mm) is provided with an ablation tip electrode at its distal end having a length ranging from about 4 mm to about 8 mm. If the ablation electrode is provided in perpendicular relation to the tissue, a relatively small surface area of the electrode is in contact with the tissue. In contrast, a relatively larger surface area would be in contact with the tissue if the ablation electrode were in a generally parallel relationship to the tissue, i.e., if the ablation electrode were positioned on its side. The size of the lesion is often related to the amount surface area in contact with the tissue and there can be significant energy loss through the portion of the electrode not in contact with any tissue, particularly since blood has a higher conductivity than tissue.

Moreover, overheating of the tip electrode can cause complications, including the formation of char and/or thrombus on the electrode surface. The creation of char and thrombus is unsafe, as the char and thrombus can be dislodged from the electrode during the procedure or during removal of the catheter after the procedure.

SUMMARY OF THE INVENTION

The present invention is directed to a system, a method and a catheter that provide improved ablation capabilities and improved energy efficiency by selectively energizing catheter electrodes on the basis of impedance measurements. In particular, the invention is directed to the selective energization of catheter radial electrodes that together with a tip electrode form a generally continuous tissue contact surface, wherein the selection is made on the basis of impedance measurement as an indication of the amount of tissue contact of each radial electrode.

The system for selectively energizing electrodes on a catheter includes a catheter having a catheter body, and a tip section carrying a tip electrode and a plurality of radial electrodes and a return electrode. There are also a signal generator to provide impedance test signals and a multiplexer adapted to operate in a first mode wherein the multiplexer continuously changes electrical connection between the signal generator to a specific radial electrode, and a second mode wherein the multiplexer connects the signal electrode to a selected radial electrode. Further included in the system are an impedance measurement circuitry adapted to provide impedance measurements of each radial electrodes as an indication of tissue contact, and a microcontroller adapted to command the multiplexer to operate in said first mode or said second mode. An ablation energy source is also provided to energize the tip electrode and the selected radial electrode.

The method of the present invention includes providing a catheter having a catheter body, and a tip section carrying a tip electrode and a plurality of radial electrodes proximal the tip electrode, and providing a return electrode. The method further includes providing a signal generator adapted to generate impedance test signals, and changing electrical connection between the signal generator and a specific radial electrode. The method further includes obtaining impedance measurement for each radial electrode when it is receiving impedance test signals as an indication of tissue contact, and identifying the radial electrode with the highest impedance measurement. The method further includes maintaining electrical connection between the signal generator and the radial electrode with the highest impedance measurement the exclusion of remaining radial electrodes, and applying ablation energy to the radial electrode with the highest impedance to the exclusion of nonselected radial electrodes.

A catheter of the present invention includes a catheter body having an outer wall, proximal and distal ends, and a single central lumen extending therethrough and a control handle at the proximal end of the catheter body. Also included are a tip section comprising a segment of flexible tubing having proximal and distal ends and at least one lumen therethrough, the proximal end of the tip section being fixedly attached to the distal end of the catheter body, and a tip electrode fixedly attached to the distal end of the tubing of the tip section. Moreover, a plurality of radial electrodes are fixedly attached to the tubing immediately proximal the tip electrode, wherein each radial electrode is configured to form a specific generally continuous tissue contact surface with the tip electrode.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. **1** is a side elevational view of an embodiment of a catheter in accordance with the present invention;

FIG. **2** is a side cross sectional view of an embodiment of a catheter body and an intermediate section taken along a first diameter;

FIG. **2**A is a side cross sectional view of the catheter body and intermediate section of FIG. **2** taken along a second diameter generally perpendicular to the first diameter;

FIG. **3**A is a side cross sectional view of an embodiment of the intermediate section and a tip section taken along a first diameter;

FIG. **3**B is a side cross sectional view of the intermediate section and the tip section of FIG. **3**A, taken along a second diameter generally perpendicular to the first diameter;

FIG. **3**C is a longitudinal cross sectional view of the intermediate section of FIG. **3**A, taken along line **3**C-**3**C;

FIG. **4**A is a side cross sectional view of an embodiment of a tip section;

FIG. **4**B is a longitudinal cross-sectional view of the tip section of FIG. **4**A taken along line **4**B-**4**B;

FIG. **5** is a schematic perspective view of an embodiment of the catheter of the present invention in tissue contact for ablating and creating a lesion;

FIG. **6** is a side cross-sectional view of an embodiment of a control handle;

FIG. **7** is a schematic diagram of an embodiment of a system for selectively energizing catheter electrodes in accordance with the present invention; and

FIG. **8** is a flow chart illustrating schematically a method of selectively energizing catheter electrodes in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides a system and method and a catheter for use therewith that ablates with improved energy efficiency. The invention is directed to the selective energization of catheter radial electrodes that together with a tip electrode form a generally continuous tissue contact surface, wherein the selection is made on the basis of impedance measurement as an indication of the amount of tissue contact of each radial electrode.

With reference to FIG. **1**, the catheter **10** comprises an elongated catheter body **12** having proximal and distal ends, an intermediate section **14** at the distal end of the catheter body, a control handle **16** at the proximal end of the catheter body, and an irrigated tip section **26** at the distal end of the catheter body. The tip section carries a tip electrode **28** and a plurality of radial electrodes **37** immediately proximal the tip electrode. The tip section **26** of the catheter may also carry an electromagnetic location sensor **72** to determine the position and orientation of the catheter within the patient's body.

With reference to FIGS. **2** and **2**A, the catheter body **12** comprises an elongated tubular construction having a single, axial or central lumen **18**. The catheter body **12** is flexible, i.e., bendable, but substantially non-compressible along its length. The catheter body **12** can be of any suitable construction and made of any suitable material. A presently preferred construction comprises an outer wall **20** made of polyurethane or PEBAX. The outer wall **20** comprises an imbedded braided mesh of stainless steel or the like to increase torsional stiffness of the catheter body **12** so that, when the control handle **16** is rotated, the intermediate section **14** of the catheter **10** will rotate in a corresponding manner.

The outer diameter of the catheter body **12** is not critical, but is preferably no more than about 8 french, more preferably 7 french. Likewise the thickness of the outer wall **20** is not critical, but is thin enough so that the central lumen **18** can accommodate at least a puller wire **50**, lead wires **40**, **42** and **44**, a first irrigating tube segment **88**, a sensor cable **74**. If desired, the inner surface of the outer wall **20** is lined with a stiffening tube **22** to provide improved torsional stability. The proximal end of the stiffening tube **22** is affixed to the outer wall by glue joint **15**. The distal end of the stiffening tube **22** is affixed to the outer wall by glue joint **17**. A particularly preferred catheter has an outer wall **20** with an outer diameter of from about 0.090 inch to about 0.94 inch and an inner diameter of from about 0.061 inch to about 0.065 inch.

As shown in FIGS. **3**A, **3**B and **3**C, the intermediate section **14** distal the catheter body **12** comprises a short section of tubing **19** having multiple lumens. A first lumen **30** carries the electrode lead wires **40**, **42** and **44**. A second lumen **32** carries the puller wire **50**. A third lumen **34** carries the sensor cable **74** for the electromagnetic location sensor **72**. A fourth lumen **36** allows passage of fluid transported in the first infusion tube segment **88** and carries a proximal portion of a second infusion tube **89** whose distal end is in the tip electrode **28**. The tubing **19** is made of a suitable nontoxic material that is preferably more flexible than the catheter body **12**. A presently preferred material for the tubing **19** is braided polyurethane, i.e., polyurethane with an embedded mesh of braided stainless steel or the like. The size of each lumen is not critical, but is sufficient to house the lead wires, puller wire, the sensor cable or any other components.

The useful length of the catheter, i.e., that portion that can be inserted into the body can vary as desired. Preferably the useful length ranges from about 110 cm to about 120 cm. The length of the intermediate section **14** is a relatively small portion of the useful length, and preferably ranges from about 3.5 cm to about 10 cm, more preferably 6 from about 5 cm to about 6.5 cm.

A preferred means for attaching the catheter body **12** to the intermediate section **14** is illustrated in FIG. **2**. The proximal end of the intermediate section **14** comprises an outer circumferential notch **24** that receives the inner surface of the outer wall **20** of the catheter body **12**. The intermediate section **14** and catheter body **12** are attached by glue or the like.

If desired, a spacer (not shown) can be located within the catheter body between the distal end of the stiffening tube **22** (if provided) and the proximal end of the intermediate section **14**. The spacer provides a transition in flexibility at the junction of the catheter body **12** and intermediate section **14**, which allows this junction to bend smoothly without folding or kinking. A catheter having such a spacer is described in U.S. Pat. No. 5,964,757, the disclosure of which is incorporated herein by reference.

Referring to FIGS. **4**A and **4**B, at the distal end of the intermediate section **14** is the tip section **26**. Preferably the tip section **26** has a diameter about the same as the outer diameter of the tubing **19**. In the illustrated embodiment, the tip section **26** has the tip electrode **28** and a plastic housing or a short section of tubing **35** proximal the tip electrode **28** for housing the location sensor **72**. The proximal end of the plastic housing **35** is received by a circumferential notch **25** (FIGS. **3**A and **3**B) formed in the distal end of the tubing **19** and is bonded thereto with polyurethane glue or the like. Preferably the plastic housing is about 1 cm long.

The tip electrode **28** is generally solid, having a fluid passage **38**. In the embodiment shown, the fluid passage **38** comprises an axial branch **47** and a plurality of transverse branches **48** that extend radially from the distal end of the axial branch to the outer surface of the tip electrode **28**. It is understood that the configuration of the fluid passage may vary as desired.

Formed in the proximal end of the tip electrode **28** is a blind hole **31** that generally corresponds in location to the second lumen **32** carrying the puller wire **50**. As described in further detail, the distal end of the puller wire and the distal end of the lead wire **40** that connects to the tip electrode **28** can both be anchored in the blind hole **31**. A preferred tip electrode has an effective length, i.e., from its distal end to the distal end of the tubing **35**, of about 3.5 mm, and an actual length, i.e., from its distal end to its proximal end, of about 4.0 mm.

The tip electrode **28** is attached to the plastic housing **35** by a stem **41** formed in the proximal end of the tip electrode **28**, which is received by the distal end of the tubing **35**. The stem **41** is affixed with adhesive, glue or the like. The puller wire **50** and the lead wire **40** help keep the tip electrode **28** in place on the tip section **26**.

In accordance with the present invention, the tip section **26** carries a plurality of generally equi-sized and equi-angularly spaced, elongated radial electrodes **37***i*. The electrodes **37***i* are mounted on the tubing **35** of the tip section **26** and in a side-by side configuration to jointly span about 360 degrees around the tubing **35**. A longitudinal gap between each radial electrodes is provided to electrically isolate each radial electrode from its adjacent radial electrodes. The gap may be filled with a non-conducting material **43**, for example, polyurethane. As such, the electrodes **37***i* cover nearly the entire circumference of the tubing. Moreover, the distal ends of the electrodes **37***i* are immediately proximal the tip electrode such that the tip electrode **28** and at least one radial electrode **37***i* form a generally continuous elongated contact surface **53** with tissue **54** when the tip section **26** is oriented at a nonperpendicular angle. As shown in FIG. **5**, the radial electrode **37***b* together with the tip electrode **28** enable the creation of a larger lesion **59** by providing a larger, generally continuous contact surface **53** with the tissue **54**. Depending on the tissue surface contour, the size of the generally continuous contact surface **53** is typically at a minimum where the tip section **26** is generally perpendicular or about 90 degrees to the tissue surface **55** and increases with decreasing angle of the tip section **28** to the tissue surface **55**, with a maximum contact surface area where tip section **26** is generally parallel with the tissue surface **55**, lying on it, at or about 0 degrees.

As discussed further below, the present invention provides for selective energization of the radial electrode (e.g., electrode **37***b* in FIG. **5**) that has the most tissue contact for improved energy efficiency during ablation. That is, by withholding the ablation energy from those radial electrodes with less or no tissue contact (e.g., electrodes **37***a*, **37***c* and

37*d* in FIG. **5**), the energy is applied with discretion to minimize energy loss to the surrounding blood. In accordance with a feature of the invention, by providing n number of radial electrodes **37***a*-**37***n*, each radial electrode possesses a (1/n) fraction of the circumferential tissue contact surface of the catheter tip section. And, by supplying the ablation energy through only one radial electrode (namely, the one having the greatest tissue contact), the 1/n surface area of that radial electrode, by definition, increases the current density, whereupon a higher current density permits lower power usage and greater efficiency by the catheter **10**.

Because of the location of the tip electrode, it generally makes good tissue contact, particularly, when it is depressed into the tissue as shown in FIG. **5**. Accordingly, in the disclosed embodiment, the tip electrode **28** consistently receives the ablation energy whenever the ablation energy is applied by the operator and is not subject to this discretionary process.

Moreover, by selectively energizing the radial electrodes, the tip section **26** is rendered less prone to overheating and therefore the tissue is less susceptible to the risks associated with overheating, such as char and thrombus.

It is understood by one of ordinary skill in the art that the number of radial electrodes may be varied and can range between at least two to about eight, provided the electrodes jointly span about 360 degrees around the tubing **35** to cover its circumference. In the illustrated embodiment, there are four “quadrant” electrode **37***a*-**37***d*, each generally rectangular and spanning about 90 degrees around the tubing **35**. The length of each radial electrode may range between about 4.0 mm and 10 mm, and preferably is about 8.0 mm. It is understood by one of ordinary skill in the art that the width of each radial electrode depends on the size of the catheter tip section and the number of radial electrodes.

There may also be ring electrodes **56** carried on the distal section of the tubing **19** of the intermediate section **14**. In the illustrated embodiment, there are three ring electrodes proximal of the radial electrodes **37**. The ring electrodes **56** allow an operator to collect electrophysiological data from the tip section **36** of the catheter **10**. Accordingly, the presence and number of ring electrodes **56** can vary as desired.

The tip electrode **28**, the radial electrodes **37** and the ring electrodes **56** can be made of any suitable material, for example, from machined platinum-iridium bar (90% platinum/10% iridium).

Each of the tip electrode **28**, the radial electrodes **37**, and the ring electrodes **56** is connected to a separate lead wire. The lead wires **40**, **42** and **44** extend through the first lumen **30** of intermediate section **14**, the central lumen **18** of the catheter body **12**, and the control handle **16**, and terminate at their proximal end in an input jack (not shown) that may be plugged into an appropriate monitor (not shown). The portion of the lead wires **40**, **42**, **44** extending through the central lumen **18** of the catheter body **12**, control handle **16** and the intermediate section **14** are enclosed within a protective, nonconducting sheath **39**, which can be made of any suitable material, preferably polyimide. The sheath **39** is anchored at its distal end to the distal end of the intermediate section **14** by gluing it in the first lumen **30** with polyurethane glue or the like. In the illustrated embodiment, there are two sheaths **39**A and **39**B. The sheath **39**A is dedicated to the lead wire **40** for the tip electrode **28** and the lead wires **44** for the ring electrodes **56**. The sheath **49**B is dedicated to the lead wires **42** for the radial electrodes **37**. The distal end of sheath **39**B is proximal of the most proximal ring electrode **56**. The distal end of the sheath **39**A is proximal of the radial electrodes **37**.

The lead wires **44** and **42** are attached to the radial and ring electrodes **37** and **56** by any conventional technique. Connection of a lead wire to one of these electrodes is preferably accomplished by first making a small hole through the tubing **19** or **35**. Such a hole can be created, for example, by inserting a needle through the tubing and heating the needle sufficiently to form a permanent hole. A lead wire is then drawn through the hole by using a microhook or the like. The ends of the lead wire are then stripped of any coating and soldered or welded to the underside of the electrode. The electrodes may then be positioned over the hole (or slid into position over the hole in the case of the ring electrodes) and are fixed in place with polyurethane glue or the like.

The tip section **26** carries the electromagnetic location sensor **72** which is bonded in the lumen of the tubing **35**. The electromagnetic sensor cable **74** extend from the proximal end of the location sensor and through the third lumen **34** of the tip section **14**, through the central lumen **18** of the catheter body **12**, and into the control handle **16**. As shown in FIG. **1**, the electromagnetic sensor cable **74** then extends out the proximal end of the control handle **16** within an umbilical cord **98** to a sensor control module **75** that houses a circuit board (not shown). Alternatively, the circuit board can be housed within the control handle **16**, for example, as described in U.S. Pat. No. 5,964,757, the entire disclosure of which is incorporated herein by reference. The electromagnetic sensor cable **74** comprises multiple wires encased within a plastic covered sheath. In the sensor control module **75**, the wires of the electromagnetic sensor cable **74** are connected to the circuit board. The circuit board amplifies the signal received from the electromagnetic sensor **72** and transmits it to a computer in a form understandable by the computer by means of the sensor connector **77** at the proximal end of the sensor control module **75**, as shown in FIG. **1**. Also, because the catheter is designed for single use only, the circuit board may contain an EPROM chip which shuts down the circuit board approximately 24 hours after the catheter has been used. This prevents the catheter, or at least the electromagnetic sensor, from being used twice. Suitable electromagnetic sensors for use with the present invention are described, for example, in U.S. Pat. Nos. 5,558,091, 5,443,489, 5,480,422, 5,546,951, 5,568,809, and 5,391,199 and International Publication No. WO 95/02995, the disclosures of which are incorporated herein by reference. A preferred electromagnetic mapping sensor **72** has a length of from about 6 mm to about 7 mm and a diameter of about 1.3 mm.

Referring back to FIG. **2**, the puller wire **50** extends through the catheter body **12**, is anchored at its proximal end to the control handle **16** (FIG. **6**), and is anchored at its distal end to the tip electrode **28** (FIG. **4**A). The puller wire is made of any suitable metal, such as stainless steel or Nitinol, and preferably has a coating of Teflon® or the like. The coating imparts lubricity to the puller wire. The puller wire preferably has a diameter ranging from about 0.006 to about 0.010 inches.

A compression coil **52** is situated within the catheter body **12** in surrounding relation to the puller wire **50**. The compression coil **52** extends from the proximal end of the catheter body **12** to the proximal end of the intermediate section **14**. The compression coil **52** is made of any suitable metal, preferably stainless steel. The compression coil **52** is tightly wound on itself to provide flexibility, i.e., bending, but to resist compression. The inner diameter of the compression coil is preferably slightly larger than the diameter of the puller wire **50**. The Teflon® coating on the puller wire

50 allows it to slide freely within the compression coil 52. If desired, particularly if the lead wires 40, 42, 44 are not enclosed by a protective sheaths 39, the outer surface of the compression coil can be covered by a flexible, non-conductive sheath, e.g., made of polyimide tubing, to prevent contact between the compression coil 52 and any other wires within the catheter body 12.

The compression coil 52 is anchored at its proximal end to the proximal end of the stiffening tube 22 in the catheter body 12 by glue joint 51 and at its distal end to the intermediate section 14 by glue joint 57. Both glue joints 51 and 57 preferably comprise polyurethane glue or the like. The glue may be applied by means of a syringe or the like through a hole made between the outer surface of the catheter body 12 and the central lumen 18. Such a hole may be formed, for example, by a needle or the like that punctures the outer wall 20 of the catheter body 12 and the stiffening tube 22 which is heated sufficiently to form a permanent hole. The glue is then introduced through the hole to the outer surface of the compression coil 52 and wicks around the outer circumference to form a glue joint about the entire circumference of the compression coil 52.

As shown in FIG. 4A, the puller wire 50 is anchored at its distal end to the tip electrode 28 within the blind hole 31. A preferred method for anchoring the puller wire 50 within the tip electrode 28 is by crimping metal tubing 46 to the distal end of the puller wire 50 and soldering the metal tubing 46 inside the blind hole 31. Anchoring the puller wire 50 within the tip electrode 28 provides additional support, reducing the likelihood that the tip electrode 28 will fall off the tip section 26. Alternatively, the puller wire 50 can be attached to the tubing 35 of the tip section 26, or the distal section of the tubing 19 of the intermediate section 14. Within the second lumen 32 of the intermediate section 14, the puller wire 50 extends through a plastic, preferably Teflon®, sheath 58, which prevents the puller wire 50 from cutting into the wall of the tubing 19 when the intermediate section 14 is deflected.

Longitudinal movement of the puller wire 50 relative to the catheter body 12, which results in deflection of the intermediate section 14, is accomplished by suitable manipulation of the control handle 16. As shown in FIG. 6, the distal end of the control handle 16 comprises a piston 60 with a thumb control 62 for manipulating the puller wire 50. The proximal end of the catheter body 12 is connected to the piston 60 by means of a shrink sleeve 64.

The puller wire 50, lead wires 40, 42, 44, the sensor cable 74 extend through the piston 60. The puller wire 50 is anchored to an anchor pin 66, located proximal to the piston 60. Within the piston 60, the sensor cable 74 extends into another protective sheath 91, preferably made of polyurethane. The protective sheathes 39A, 39B and 91 are anchored to the piston 60, preferably by polyurethane glue or the like at a glue joint 63, allowing the lead wires 40, 42, 44 and the sensor cable 74 longitudinal movement within the control handle 16 so that they do not break when the piston 60 is adjusted to manipulate the puller wire 50. Within the piston 60, the puller wire 50 extends through a transfer tube 27, preferably a polyimide tube, to allow longitudinal movement of the puller wire near the glue joint 63.

The mechanics and operation of the control handle are described in U.S. Pat. No. 6,602,242, the entire disclosure of which is incorporated herein by reference. It is understood by one of ordinary skill in the art that other control handles for manipulating the puller wire or puller wires (for bi-directional deflection) may be used with the present catheters.

FIG. 7 illustrates a system 100 for performing ablation using the catheter 10 in selectively energizing the radial electrode having the greatest tissue contact as identified by the system on the basis of impedance measurements. Each of the radial electrodes 37*i* is connected by a separate lead wire 42*i* to the catheter handle 16 from which electrical connections are made to the system 100. A signal generator (SG) 102 sends a high frequency test signal, e.g., an alternating current (AC) signal at about 2 μamps, in the frequency range of about 10 kHz to about 100 kHz, preferably about 50 kHz, to a multiplexer 104 via a high output impedance buffer (IB) 106. The multiplexer 104 has multiple channels 108*i*, each of which is in communication with a specific radial electrode 37*i* to receive the same current.

A return electrode 110 is also driven by the signal generator 102. The signal to the return electrode 110 is first inverted in phase by inverter 112 and conditioned by high output impedance buffer (IB) 114.

In accordance with a feature of the invention, the system 100 provides an impedance measurement circuitry (IMC) 115 to measure the impedance of each radial electrode as an indicator of the extent of tissue contact of each radial electrode. By energizing only the radial electrode with the greatest impedance measurement, that selected radial electrode and the tip electrode form a greater tissue contact surface than the tip electrode would by itself and the ablation energy is not wasted on other radial electrodes that have no or lesser tissue contact. The impedance measurement circuitry 115 includes a differential amplifier (DA) 116, an amplifier (AMP) 118 and a synchronous detector (SD) 120. The differential amplifier 116 measures a difference signal, specifically the voltage across a selected radial electrode 37*i* and the return electrode 110. The difference signal is further amplified by the amplifier 118 whose output is send to the synchronous detector 120 which transforms the AC signal into a direct current (DC) signal and also decreases the sensitivity of the system 100 to external noise. The signal from the synchronous detector 120 is then used by a microcontroller 122 to control the multiplexer 104. To that end, the microcontroller continuously stores in a memory 124 a plurality of different impedance signals from the synchronous detector 120 that equals the plurality of channels 108*i* in the multiplexer 104 (which is at least the plurality of radial electrodes 37*i* on the catheter 10), along with identification information on the channels 108*i* associated with each impedance value stored. As such, the microcontroller 122 is at any time capable of identifying the channel 108*i* (and hence the radial electrode 37*i*) exhibiting the highest impedance value, which should be the radial electrode 37*i* with the greatest tissue contact.

With reference to the flow chart of FIG. 8, the system 100 in operation as implemented by the microcontroller 122 is described as follows. Under fluoroscopic guidance, or other suitable guidance means, the catheter is introduced into the patient's body. The catheter is advanced into the patient's heart through appropriate vascular access and positioned inside the heart chamber. The system 100 and microcontroller 122 are powered up (Block 130). The microcontroller 122 is activates the signal generator and commands the multiplexer to operate in the "switch" mode (Block 132), whereby the multiplexer constantly switches between the channels 108*i* and allows passage of the impedance test signal from the signal generator 102 to only one radial electrode 37*i* at any given time (Block 134). The impedance measurement circuitry 115 measures the impedance of each radial electrode 37*i* as the multiplexer 108 switches between the different channels 108*i* (Block 136) and the impedance measurements are stored in the memory which is constantly being updated with new impedance measurements of each radial electrode.

When the operator of the catheter is ready to ablate, he triggers an input, e.g., a push-to-activate contact **129** (FIG. **7**) or the like (Query **138**), which signals the microcontroller **122** to access the memory **124** and identify the channel **108** with the greatest impedance value (Block **140**). If there are more than one radial electrode with the same greatest impedance measurement (Block **141**), the microcontroller **122** selects the most recent radial electrode with the greatest impedance measurement (Block **142**). In any event, the microcontroller **122** then commands the multiplexer **104** to switch to a "lock" (or "stationary") mode and the connection of the multiplexer remains on the identified channel (Block **143**) for the duration of the ablation session.

The microcontroller **122** then enables the ablation power source (PS) **126** and the switch **128** (Block **144**) which energizes the tip electrode **28** and allows the ablation current to pass to the selected radial electrode whose lead is receiving the current from the multiplexer **104** (Block **146**). The combined contact surface of the tip electrode **28** and the selected radial electrode **37***i* creates a larger lesion with improved energy efficiency because the ablation current is directed to the tip electrode **28** and only the radial electrode **37***i* with the most tissue contact.

When the operator completes the ablation session, he releases the button or switch and the microcontroller **122** deactivates the ablation power source **126** and the switch **128** (Block **150**) and returns the multiplexer **104** to operation in the "switch" mode (Block **132**). Thus, the multiplexer **104** returns to constantly switching between its channel **108***i* to allow the test signal from the signal generator **102** to pass through the different channels onto each radial electrode **37***i*. The microcontroller **122** returns to receiving impedance signals of each radial electrode **37***i* from the impedance measurement circuitry **115** and constantly storing and refreshing the impedance values in the memory **124**, along with the identification information of the channel associated with each stored impedance values.

The preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology to which this invention pertains will appreciate that alterations and changes to the described structure may be practiced without meaningfully departing from the principal, spirit and scope of this invention. Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support for the following claims which are to have their fullest and fairest scope.

What is claimed is:

1. A catheter comprising:

an elongated catheter body; and

a tip section having a tip electrode and two or more elongated secondary electrodes proximal of the tip electrode, the two or more secondary electrodes being arranged in a side-by-side configuration to jointly span about 360 degrees around the tip section and being positioned such that each of the two or more elongated secondary electrodes forms a different continuous elongated electrode surface with the tip electrode, and the two or more secondary electrodes being configured for selective energization.

2. The catheter according to claim **1**, wherein each of the two or more elongated secondary electrodes are separated from each other elongated secondary electrode by a gap.

3. The catheter according to claim **2**, wherein the gap includes a non-conducting material.

4. The catheter according to claim **1**, wherein the two or more elongated secondary electrodes comprises four elongated secondary electrodes.

5. The catheter according to claim **1**, further comprising a different lead wire for each of the two or more elongated secondary electrodes.

6. The catheter according to claim **1**, wherein each of the two or more elongated secondary electrodes extends longitudinally along the tip section with a distal end immediately proximal the tip electrode.

7. A system for ablating tissue, comprising:

the catheter of claim **1**;

a signal generator configured to generate impedance test signals;

an impedance measurement circuitry configured to generate impedance measurements of each of the two or more elongated secondary electrodes;

a multiplexer configured to connect the signal generator to a selected one of the two or more elongated secondary electrodes in response to the impedance measurements; and

an ablation energy source configured to energize the tip electrode and the selected one of the two or more elongated secondary electrodes.

8. The system according to claim **7**, wherein each of the two or more elongated secondary electrodes extends longitudinally along the tip section with a distal end immediately proximal the tip electrode.

9. The system according to claim **7**, wherein the tip electrode is irrigated.

10. The system according to claim **7**, wherein the ablation energy source is configured to deliver ablation energy to the selected one of the two or more elongated secondary electrodes to the exclusion of remaining ones of the two or more elongated secondary electrodes.

11. The system according to claim **7**, further comprising a return electrode.

12. The system according to claim **7**, further comprising a memory configured to store the impedance measurements.

13. The system according to claim **12**, wherein the memory is continuously refreshed with new impedance measurements.

14. The system according to claim **7**, wherein the two or more elongated secondary electrodes comprises four elongated secondary electrodes.

15. A method of ablating tissue, comprising:

introducing to the tissue the catheter of claim **1**;

obtaining impedance measurements for each of the two or more elongated secondary electrodes;

identifying which one of the two or more elongated secondary electrodes has the highest impedance measurement; and

applying ablation energy to the one of the two or more elongated secondary electrodes with the highest impedance measurement to the exclusion of remaining ones of the two or more elongated secondary electrodes to thereby ablate the tissue.

16. The method according to claim **15**, wherein each of the two or more elongated secondary electrodes is configured to form a different tissue contact surface with the tip electrode.

17. The method according to claim **15**, wherein the tip electrode is irrigated, and the method further comprises irrigating the tip electrode.

18. The method according to claim **15**, further comprising storing the impedance measurements in a memory.

19. The method according to claim **18**, further comprising continuously refreshing the memory with new impedance measurements.

20. The method according to claim **1**, wherein the two or more elongated secondary electrodes comprises four elongated secondary electrodes.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 11,213,346 B2
APPLICATION NO. : 16/357230
DATED : January 4, 2022
INVENTOR(S) : Eduardo Jimenez

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Claims

Column 13, Line 9, Claim 20 Delete "claim 1",
Insert -- claim 15, --

Signed and Sealed this
Seventeenth Day of January, 2023

Katherine Kelly Vidal

Katherine Kelly Vidal
Director of the United States Patent and Trademark Office